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APPLICATION NO.	FILIN	NG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/590,139	02/	11/2008	Neil Duggal	HO-P03203US0	5647	
IMDS, INC.	7590	06/15/2011		EXAMINER		
124 SOUTH 600 WEST				SNOW, BRUCE EDWARD		
LOGAN, UT 84321				ART UNIT	PAPER NUMBER	
				3738		
				NOTIFICATION DATE	DELIVERY MODE	
				06/15/2011	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail  $\,$  address(es):

khansen@imds.net

## Office Action Summary

Application No.	Applicant(s)	
10/590,139	DUGGAL ET AL.	
Examiner	Art Unit	
BRUCE E. SNOW	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -- Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,

- WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
   Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
- earned patent term adjustment. See 37 CFR 1.704(b).

- 1) Responsive to communication(s) filed on 06 April 2011.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
  - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 32-38,41,43-45,48,50-56,58,60,61,63-66 and 68-73 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 32-38.41.43-45.48.50-56.58.60.61.63-66 and 68-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some \* c) ☐ None of:
    - Certified copies of the priority documents have been received.
    - Certified copies of the priority documents have been received in Application No.
    - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of Fielerances Cited (PTO-592)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO/SB/08)
  - Paper No(s)/Mail Date

- Interview Summary (PTb-413)
   Paper No(s)/Mail Date.
- 5) Notice of Informal Patent Application
- 6) Other:

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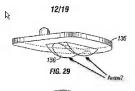
#### DETAILED ACTION

### Response to Arguments

Applicant's arguments filed 4/6/11 have been fully considered. Note the new grounds of rejection below.

### Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "pair of spaced apart structure, such as arms" and "pair of arms (claim 58)". It is the examiner's position that applicant is referring to the noted elements. Please confirm.



Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the

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changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: first bearing surface, second bearing surface, third bearing surface, fourth bearing surface, angled section, first straight section, second straight section, first convexly curved section.

### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1993); In re Goodman, 11 F.3d 14046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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All claims are provisionally rejected on the ground of nonstatutory obviousnesstype double patenting as being unpatentable over all claims of copending Application
No. 12/241,326, 12/041,910 and 11/534,014. Although the conflicting claims are not
identical, they are not patentably distinct from each other. Applicant is has elected to
prosecute the same species in all cases. The same species contain the same

All claims are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7,927,374. Although the conflicting claims are not identical, they are not patentably distinct from each other both claiming the same elected species comprising the same limitations. The following is the allowed claim 1 from U.S. Patent No. 7,927,374:

1. An intervertebral disc prosthesis comprising: a first end plate securable to a first vertebral body of a portion of a spine, the first end plate comprising a first articular surface; a second end plate securable to a second vertebral body of the portion of the spine, the second end plate comprising a fourth articular surface; and a nucleus positioned between the first and second end plates, the nucleus formed separately from the first and second end plates, the nucleus comprising a second articular surface that articulates with the first articular surface and a third articular surface that articular surface; wherein the nucleus comprises an asymmetrical shape across a coronal plane of the first and second vertebral bodies, the asymmetrical shape tending to urge the first and second end plates to remain in a relative orientation that provides a preferred lordotic or kyphotic angle between the first and second vertebral

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bodies; wherein line contact is provided between the first and second articular surfaces when the first articular surface articulates relative to the second articular surface in the anterior/posterior direction; and wherein the third and fourth articular surfaces are substantially entirely planar to permit translational movement in at least one of the anterior-posterior and medial-lateral directions.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### Claim Rejections - 35 USC § 112

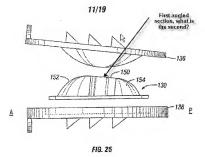
The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-38, 64,65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 32, "first and second bearing surfaces positioned between the first and second bone engagement surface, at least one of the first and second bearing surfaces comprises an angled section" is indefinite. It can be interpreted that bearing surface 150 comprises and an angled section relative to the lower plate 138. But what is the second bearing surface which comprises an angled section? Why is it considered angled? Additionally, the claim language implies that is might be angled or might not be angled. Which is correct?

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Applicant's claims use very broad claim terminology which is not supported by the specification. Due to the very broad language which confusingly can be describing various surfaces, or portions thereof, the claim is indefinite. The following claim limitations are indefinite: first and second articulating surfaces, third and fourth articulating surfaces.

As far as the scope can be determined, the following rejections are made of record.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

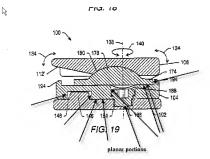
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 32-38, 64-65 are rejected under 35 U.S.C. 102(e) as being anticipated Krueger et al (2006/0116768).

Krueger et al teaches an intervertebral disc prosthesis comprising first and second endplate members 102, 106 and a nucleus 104, 174. Said first and second endplates having first bone engagement surfaces (self-evident) and further having first and second engagement feature which can be broadly interpreted as being flat, elements 108 in figure 18, etc. The prosthesis further comprising numerous bearing surfaces including 186 (indentified as 174 in the figure below) which can be interpreted as having "an angled section" having a constant slope from anterior to posterior.

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As shown in the figure above, the prosthesis further comprises numerous third and fourth bearing surfaces which have planar portions. The bearing surfaces cooperated to provide a "preferred" lordotic angle.

Claims 32-38, 41, 43-45, 48, 50, 68, 69, are rejected under 35 U.S.C. 102(a, e) as being clearly anticipated Baynham et al (7,850,733).

Baynham et al teaches an intervertebral disc prosthesis comprising first and second bone engagement surfaces (self-evident) and a nucleus 42 positioned therebetween. Said nucleus having a first bearing surface having a first straight portion (self-evident) opposite a planar bearing surface (self-evident) which are non-zero slope relatively oriented.

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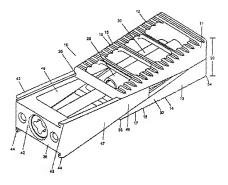


Fig. 1

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRUCE E. SNOW whose telephone number is (571)272-4759. The examiner can normally be reached on Monday - Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Bruce E Snow/ Primary Examiner, Art Unit 3738